

15. The process of claim 11, wherein the elimination of R² and R³ is performed by treatment with tetrabutyl ammonium fluoride.

16. The process of claim 11, wherein the deoximation is performed by using sodium hydrogen sulfite.

17. The process of claim 11, wherein the deoximation is performed by using titanium trichloride-ammonium acetate.

18. The process of claim 11, wherein the deoximation is performed by using sodium nitrate-hydrochloric acid.

19. The process of claim 11, wherein the deoximation is performed by using sodium hydrosulfite.

REMARKS

By the above amendment, claims 1-19 are presented for examination. Support for new claims 6-19 is provided in the specification at, for example, column 4, lines 53-60, and column 5, lines 22-30. No new matter is introduced by this amendment.

Applicants acknowledge and thank the examiner for allowance of claim 1.

Claims 2-5 were rejected under 35 U.S.C. § 112, ¶ 1, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The learned examiner rejected claims 2-5 on grounds that the terminology "eliminating" was not supported by the written description. Support for "eliminating" is found in the specification at column 4, lines 43-47, and at column 5, lines 20-21. Applicants respectfully traverse this § 112, ¶ 1 rejection.

The examiner rejected claims 2-5 on grounds that the terminology "deoximating agent" was not supported by the written description. Support for "deoximating agent" is found at

column 5, lines 22-30, where a variety of deoximating agents are listed as examples, and other agents are referred to as "and the like."

The examiner rejected claims 2-5 on grounds that deoximation by "the use of any deoximating agent" was not supported by the written description, because the written description refers to "sodium hydrogen sulfite, titanium trichloride-ammonium acetate, sodium nitrate-hydrochloric acid, sodium hydrosulfite, and the like" as deoximating agents. First, the phrase "and the like" shows that Applicants recognized, at the time of filing, that there were other deoximating agents, and that deoximation was not limited to the specific agents listed as examples.

Second, at the time of filing, one of ordinary skill in the art would know that numerous methods of deoximation were available. Attached as Ex. A is an excerpt from the well-recognized treatise Theodora W. Greene, Protective Groups in Organic Synthesis (John Wiley & Sons, Inc. 1981) ("Greene 1981"). On pages 144 through 146, numerous examples of well-known methods of deoximation are presented. One of ordinary skill in the art would know to find such well-known treatises like Greene 1981 that were available at the time of filing the original application, and would understand that the phrase "and the like" would refer to methods taught in these treatises.

Attached as Ex. B is an excerpt from the next edition of Greene—Theodora W. Greene and Peter G. M. Wuts, Protective Groups in Organic Synthesis (John Wiley & Sons, Inc., 2d ed. 1991) ("Greene 1991"). On pages 214 through 217, additional numerous examples of well-known methods of deoximation are presented. Although this is the 1991 edition, the references cited in this treatise date from prior to the filing date of the original application, and would be available to one of ordinary skill in the art.

Applicant's prior patents having overlapping inventors Morimoto, Adachi, Watanabe, and Sota demonstrate that Applicants had possession of numerous deoximating agents. For example, Applicant's U.S. Patent No. 4,990,602, attached as Ex. C, discloses numerous deoximating agents in column 7, lines 12 through 42. Applicant's U.S. Patent No. 4,672,109, attached as Ex. D, shows that the inventors recognized that deoximation of 6-O-alkyl-erythromycins could be done in a "conventional manner," as disclosed at column 4, lines 65-69.

The examiner rejected claims 2-5 on grounds that elimination of the R² and R³ trimethylsilyl (TMS) groups by any method was not supported by the written description, because the written description refers to "treatment with an acid in an alcohol or with tetrabutyl ammonium fluoride" as examples of desilylation. This rejection is respectfully traversed.

At the time of filing, one of ordinary skill in the art would know that numerous methods of desilylation were available. Attached as Ex. A is an excerpt from the well-recognized treatise Theodora W. Greene, Protective Groups in Organic Synthesis (John Wiley & Sons, Inc. 1981) ("Greene 1981"). On pages 42 through 43, numerous examples of well-known methods of desilylation of TMS groups are presented. One of ordinary skill in the art would know to find such well-known treatises like Greene 1981 that were available at the time of filing the original application.

Attached as Ex. B is an excerpt from the next edition of Greene—Theodora W. Greene and Peter G. M. Wuts, Protective Groups in Organic Synthesis (John Wiley & Sons, Inc., 2d ed. 1991) ("Greene 1991"). On pages 71 through 73, additional numerous examples of well-known methods of desilylation of TMS groups are presented. Although this is the 1991 edition, the references cited in this treatise date from prior to the filing date of the original application, and would be available to one of ordinary skill in the art.

The examiner rejected claims 2-5 on grounds that elimination of the R¹ protecting groups by any method was not supported by the written description, because the written description refers to "elimination of the R1 group ... by homogeneous or heterogeneous hydrogenolysis" as examples. This rejection is respectfully traversed.

At the time of filing, one of ordinary skill in the art would know that numerous methods of eliminating O-benzyl- and O-alkenyl oximes were available. Attached as Ex. E is an excerpt from the well-recognized treatise Jerry March, Advanced Organic Chemistry (John Wiley & Sons, Inc. 1985) ("March 1985"). On pages 784 through 786, numerous examples of well-known methods of eliminating oxime protecting groups and converting oximes to ketones are described. One of ordinary skill in the art would know to find such well-known treatises like March 1985 that were available at the time of filing the original application.

Further examples of oxime-protecting-group elimination are provided in Greene 1981 (Ex. A) on page 145 and in Greene 1991 (Ex. B) on page 216.

"In order to comply with the written description requirement, the specification 'need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed.'" All-Dental Prods., LLC. v. Advantage Dental Prods., Inc., 309 F.3d 774, 779 (Fed. Cir. 2002) (emphasis added, brackets in original), quoting Eiselstein v. Frank, 52 F.3d 1035, 1038 (Fed. Cir. 1995). Persons skilled in the art would recognize the methods of deoximation, desilylation, and elimination claimed here.

The facts here are similar to In re Peters, 723 F.2d 891, 893 (Fed. Cir. 1983), where the Federal Circuit held that in a reissue application, the written description requirement was satisfied, because persons skilled in the art would recognize that a tip's shape was not limited

to the tapered-shape examples in the patent. Here, persons skilled in the art would recognize the well-known methods of deoximation, desilylation, and elimination described in contemporaneous treatises, and thus, the written description requirement was satisfied for claims 2 through 5. For this reason, the examiner's rejection is respectfully traversed.

Applicants have also provided new claims 6-19. Applicants submit that pending claims 1-19 are allowable and request a timely issuance of a Notice of Allowance. Please feel free to call Stuart E. Pollack at (212) 336-2721 if the examiner has any questions regarding this application.